HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Refer to: CFN 1125282

M2409A

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

January 11, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

George Charles Frickel, President
Respiratory Care Associates, Inc.
712 Gorman Avenue
P.O. Box 607
Elkins, West Virginia 26241

Dear Mr. Frickel:

The Food and Drug Administration (FDA) conducted an inspection of your medical gas manufacturing facility on December 21 & 23, 1998.

That inspection found significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMP) regulations (Title 21, Code of Federal Regulations (CFR), Part 211). These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding are not in conformity with the CGMP regulations.

The deviations included the following:

- Failure to test Oxygen, U.S.P. for conformity with all appropriate specifications for identity, strength, quality, and purity prior to release.

- Failure to establish written procedures describing such operations as a quality control unit, testing and inspection procedures. distribution, training, equipment calibration and maintenance, labeling, complaints, and recalls.

- Failure to document the pre-fill, fill, and post-fill inspections conducted on each high pressure cylinder used to package Oxygen, U.S.P.

- Failure to document that each person engaged in the transfilling of compressed Oxygen, U.S.P. has the education, training, or experience to enable that person to perform their assigned function.

- Failure to identify the Oxygen, U.S.P. cylinders with a lot or control number that permits determination of the history of the manufacture and control of the batch.

At the conclusion of the inspection, Ms. Tammy S. Phillips, Administrative Assistant was presented with a written list of inspectional observations (FDA-483) which was discussed with her and Mr. Michael D. Bond, Delivery Technician. A copy of the FDA-483 is enclosed for your reference.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District

Enclosure

cc: West Virginia Department of Health & Human Resources
Building #3, Rm. 206, Capitol Complex
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305